

REMARKS

Applicants thank the Examiner for confirming during a telephone interview on September 11, 2003 that this first substantive office action was mistakenly labeled as FINAL.

Claims 1-72 are pending in the application. Claims 1-12, 28-38, 45-56, 61-65, 69 and 70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 19-24, 42, 43, and 57-60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The examined claims are also rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson et al. (Selective Photothermolysis), Chen et al., Knowlton et al. ('836), and Knowlton et al ('276).

Claims 13, 19, 21, 22, 23, 24, 42, 66 and 71 have been amended and claims 14 and 15 has been cancelled without prejudice. While Applicants believe that the originally presented claims are patentable over all of the art cited in the Office Action as well as all other references submitted by Applicants, the claims have nonetheless been amended or canceled as follows in order to expedite the application toward allowance. The amendments and cancellations are therefore made without prejudice or disclaimer, and Applicants reserve the right to pursue the original scope of the claims as provided prior to the cancellation or amendments, such as through continuation practice. Support for the amendments can be found throughout the specification and in the claims as filed. Specifically, support for the phrase "significantly greater than a thermal relaxation time (TRT) of the target area" can be found on page 5, lines 7-8. Support for the phrase "maintaining the temperature of the melanin substantially constant for the duration of the EMR application" can be found on page 8, lines 30-32. Support for the phrase "adjustable flux" can be found on page 32, lines 5-7, page 32, lines 17-23, and page 33, lines 11-12. Support for the word "change" can be found on page 8, line 11 and page 18, line 26. Accordingly, no new matter has been added by the proposed amendments.

Applicants respectfully traverse the Examiner's rejections and request reconsideration of the application in view of the amendments made above and the remarks that follow.

IDS

In the Office Action, the Examiner notes that while the file wrapper of this application indicates that four separate IDSs (two on July 25, 2001 and one on June 10, 2002 and one of January 15, 2003) have been filed, the Examiner has only been able to locate the IDS submitted on January 15, 2003. In accordance with the phone conversation with the Examiner on September 11, 2003, the Applicants submit herewith a copy of the 1449 forms for the two missing IDS's that were previously submitted, one from July 2001 and one from June 2002. A copy of the foreign patents and non-patent references were hand delivered to the Examiner on November 6, 2003 by the Applicants' Attorney, Thomas Engellenner.

Specification

The Applicants have amended the Specification, as noted, to correct the typographical error in which the priority date "January 25, 2000", was mistakenly written as "January 25, 200".

Rejections under 35 U.S.C. § 112, 2nd paragraph

Claims 19-24, 42, 43, and 57-60 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

In claims 19 and 21-24 exactly what is being claimed is unclear as the claims appear to positively recite the human body. Claims 19 and 21-24 have been amended to better define the claimed invention.

In claims such as 57-60 exactly what is intended to be claimed by the "heater portion" is unclear. The Applicants kindly direct the Examiner to page 3, line 23-33 and

page 18, lines 24-28, in which "heater portion" is defined to encompass both chromophores and "highly pigmented, strongly absorbing portions of a target area." The Examiner is respectfully requested to withdraw this rejection.

Claim 42 is indefinite as the function r is undefined in this claim and its dependents. Claim 42 is amended to eliminate the undefined term and to recite "the ratio of TDT to TRT is dependant on x and Δ , where x is a geometrical factor and Δ is a temperature factor," thus eliminating the undefined term.

In light of these amendments, Applicants respectfully request that the Examiner withdraw these rejections.

Rejections under 35 U.S.C. § 102(b)

Claims 13, 18, and 39 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson et al. (Selective Photothermolysis). Claims 13-15, 17, 18, 39, 40, 57-60 and 71 are rejected under 35 U.S.C. § 102(b) as being anticipated by Chen et al. Claims 37-41, 57, 58, 60, 66, 68, 71 are rejected under 35 U.S.C. § 102(b) as being anticipated by Knowlton et al. ('836). Claims 13-17, 39, 41 43, 57-60, 66-68, 71 and 72 are rejected under 35 U.S.C. § 102(b) as being anticipated by Knowlton et al. ('276). Based on the amendments and the following remarks, Applicants respectfully request reconsideration and withdrawal of the anticipatory rejections.

Applicants' invention relates to an apparatus for performing a medical procedure on a treatment area of a patient's body containing at least one chromophore. The apparatus includes a source of electromagnetic radiation (EMR) of at least one wavelength absorbed by the chromophore, an applicator, and controls. The controls cause the EMR applied to the target area to have a power profile with an average power sufficient to effect the desired result over the application duration and peak power which does not result in destruction of the chromophore.

Claim 13, 18, and 39 stand rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Anderson et al. (Selective Photothermolysis, *Science* Vol. 220, p. 524-7 (1983)). The Applicants respectively disagree with this rejection. Based on the following remarks, Applicants respectfully request reconsideration and withdrawal of the rejections.

Anderson et al. discloses a simple, predictive model for selectively damaging pigmented structures, cells and organelles in vivo. The disclosed technique, in pertinent part, “relies on selective absorption of a *brief* radiation pulse to generate and confine heat at certain pigmented targets” (*See* page 524). The Anderson reference specifies that nonspecific or unwanted thermal damage can occur when the laser exposure duration, or pulse width, equals or exceeds the thermal relaxation time (*See* page 525). Therefore, the Anderson reference teaches that it is preferable to use a pulse width *less than* the thermal relaxation time. On page 526 of the Anderson reference, an experiment is performed in accordance with the teachings of the reference in which vessels, which have a thermal relaxation time of about 50 μ sec, are irradiated with a laser using a pulse width of 0.3 μ sec, which is much *less than* the thermal relaxation time. In contrast, both independent claim 39 and amended independent claim 13 require “a duration significantly *greater than* said thermal relaxation time.”

Furthermore, independent claim 13, and claim 18 which depends therefrom, requires that the apparatus have controls causing the EMR applied to the target area to have a power profile with an average power (P_a) and peak power (P_p), where the peak power is “insufficient to cause a change in the at least one chromophore.” The Anderson reference does not teach or suggest irradiating with a peak power that does not cause a change in the chromophore, which results in a significant loss of absorption. The Anderson reference, in contrast, teaches maximizing selective optical absorption by the chromophore.

Because Anderson does not disclose or teach the recited limitations of the claimed invention, Applicants believe that Anderson does not anticipate, or render obvious, the

claimed invention as amended. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection over Anderson.

Claims 13-15, 17, 18, 39, 40, 57-60 and 71 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Chen et al. The Applicants respectfully disagree with this rejection as the Chen reference does not disclose each and every element of the claimed invention.

The Chen device is an apparatus to be used for *increasing perfusion of a drug* through a tissue including a probe that can be placed at the target site that is preferentially *inside the body*. The apparatus disclosed by Chen has a probe with a means for heating the tissue and/or emitting light at a waveband that “substantially overlaps a characteristic absorption waveband of the *drug delivered to the tissue* at the treatment site.” (col 2, line 56-58). The Chen device does not generate a peak power that is *insufficient to cause a change* in the at least one chromophore, which results in a significant loss of absorption, as required by the Applicants’ claims 13-15, 17, and 18, but rather the Chen device generates light that “has a characteristic waveband *corresponding* to an absorption waveband of the photoreactive agent.” (See col. 5, lines 23-25).

Furthermore, claim 39 of the Applicants’ invention requires that the apparatus have controls to apply EMR to the target area “for a duration significantly greater than said thermal relaxation time.” The Chen reference does not disclose a pulse width or duration for applying radiation to the target area. In addition, Chen does not teach or suggest the idea of determining the duration of treatment with regard to the thermal relaxation time. Therefore, the device disclosed by the Chen reference does not teach each and every element of independent claim 39 and dependent claim 40.

As amended, independent claims 57, and claims 58-60 dependent therefrom, require “controls for at least one of said source and said applicator to cause said EMR applied to the target area to have an *adjustable flux*.” The Chen reference does not teach or suggest varying or adjusting the flux.

Claim 71 recites an apparatus capable of delivering a “power profile resulting in the temperature T of said heater being *substantially constant* during said durations.” Chen does not teach maintaining a constant temperature. In contrast, Chen’s device changes temperature and monitors those changes in temperature at the treatment site (*See* Col. 3, lines 1-7). Chen teaches that “the light source can be initially energized to heat the treatment site, then de-energized until after the drug is administered, and re-energized to provide light of the required waveband” (*See* Col. 5, lines 31-34). Thus, Chen teaches increasing the temperature of the treatment area, but does not teach or suggest maintaining a *constant temperature* during the duration of the treatment.

The Chen reference does not teach each and every element of the claimed invention. Accordingly, the Examiner is respectfully requested to remove his rejections to claims 13-15, 17, 18, 39, 40, 57-60 and 71.

Claims 37-41, 57, 58, 60, 66, 68, and 71 are rejected under 35 U.S.C. § 102(b) as being anticipated by Knowlton et al. (‘836). Applicants point out that claims 37 and 38 have been withdrawn from consideration. The Applicants request reconsideration of the rejection of claims 39-41, 57, 58, 60, 66, 68, and 71 in light of the following remarks.

Knowlton ‘836 discloses a method and apparatus for applying radiant energy to the skin by creating a reverse thermal gradient utilizing one or more *RF electrodes* and an *electrolytic solution* that transfers the RF energy from the electrodes to the epidermis and underlying layers. Knowlton ‘836 teaches that the electrolytic solution reduces the amount of time needed to achieve denaturation of collagen molecules and subsequent skin tightening. Furthermore, Knowlton ‘836 teaches the creation of a reverse thermal gradient that is “different from other methods of collagen contraction which typically employ a thermal gradient that has a higher temperature at the surface and decreases with the depth of penetration.” (*See* Col. 3, lines 42-45).

Independent claim 39, and dependant claims 40-41, recite an applicator to apply EMR to the target area “for a duration significantly greater than said thermal relaxation time.” Knowlton ‘836 does not teach or suggest the idea of determining the duration of

treatment with regard to the thermal relaxation time. Therefore, the device disclosed by the Knowlton '836 reference does not teach each and every element of independent claim 39 and dependent claim 40.

As amended, independent claims 57 and 71 and dependent claim 58, require "controls for at least one of said source and said applicator to cause said EMR applied to the target area to have an *adjustable flux*." Knowlton '836 does not teach or suggest varying or adjusting the flux.

Independent claim 66 and dependant claim 68 recite an apparatus having a source of electromagnetic radiation of a wavelength that is "absorbed by melanin in the patient's epidermis." Knowlton '836 does not teach or suggest selecting a radiation that is absorbed by melanin. In fact, Knowlton '836 teaches away from the idea of using melanin as the chromophore. Melanocytes are cells in the epidermis that contain an intracytoplasmic organelle, the melanosome, in which the pigment known as melanin is produced and deposited. Knowlton '836 teaches applying radiant energy and heating the epidermis layer and the underlying collagen "without substantially effecting the melanocytes" (See Col. 2, line 63-66 and Col. 7, lines 4-5).

In addition, independent claim 66, as amended, and independent claim 71 require that the temperature be maintained "substantially constant" for the duration of the EMR application. In contrast, Knowlton '836 teaches that the "reverse thermal gradient provides a variation in temperature throughout the various tissue layers" (See Col. 7, lines 17-18).

As discussed above, Knowlton '836 does not disclose or teach each element of the claimed invention. Accordingly, the Examiner is respectfully requested to remove his rejections to claims 13-15, 17, 18, 39, 40, 57-60 and 71.

Claims 13-17, 39, 41, 43, 57-60, 66-68, 71 and 72 are rejected under 35 U.S.C. § 102(b) as being anticipated by Knowlton '276. Applicants note that Knowlton '276 should not be used as a basis of a rejection under 35 U.S.C. § 102(b) since Knowlton

'276 was published on February 26, 2002, which is *less than one year* from the filing of the Applicants' application on January 25, 2001. Applicants assume that the Examiner meant to reject claims 13-17, 39, 41, 43, 57-60, 66-68, 71 and 72 under 35 U.S.C. § 102(e) and present the arguments below to distinguish Applicants' invention over Knowlton '276.

Knowlton '276 discloses an apparatus for remodeling collagen through the delivery of mechanical force and/or electromagnetic energy to a tissue.

Independent claims 13 and 39, and respective dependant claims 14-17 and 41 and 43, recite an application to apply EMR to the target area "for a duration significantly greater than said thermal relaxation time." Knowlton '276 focuses on *mechanical* relaxation, defined as the "reforming of hydrogen bonds" (Col. 10, lines 54-56) of collagen fibrils, as opposed to *thermal* relaxation of the tissue as disclosed by the Applicants. Thus, Knowlton '276 does not teach or suggest the idea of selecting the *duration* of treatment such that it exceeds the *thermal* relaxation time.

As amended, independent claims 57 and 71 and dependent claims 58-60 and 72 require "controls for at least one of said source and said applicator to cause said EMR applied to the target area to have an *adjustable flux*." Knowlton '276 does not teach or suggest varying or adjusting the flux.

Independent claim 66 and dependant claims 67 and 68 recite an apparatus having a source of electromagnetic radiation of a wavelength that is "absorbed by melanin in the patient's epidermis." Knowlton '276 does not teach or suggest selecting a radiation that is specifically absorbed by melanin.

Since Knowlton '276 does not disclose or teach all of the limitations of the claimed invention, Knowlton '276 does not anticipate (or render obvious) the claimed invention as amended. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection over Knowlton '276.


CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

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